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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,011	09/30/2003	Lynn Dickey	040989/267934(9280-12A)	5538

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ALSTON & BIRD LLP  
BANK OF AMERICA PLAZA  
101 SOUTH TRYON STREET, SUITE 4000  
CHARLOTTE, NC 28280-4000

EXAMINER
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ZHENG, LI

ART UNIT	PAPER NUMBER
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1638

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05/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/675,011	<b>Applicant(s)</b> DICKEY ET AL.	
	<b>Examiner</b> Li Zheng	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 44-96 is/are pending in the application.
- 4a) Of the above claim(s) 44-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 82-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
: 3242005/2102005/11-1-2004/9302003.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of claims 82-84, SEQ ID NO: 16 and antibody, and submission of new claims 85-96 are acknowledged in the reply filed on 3/21/2007. During the phone conversation of March 19 and 20, Applicants requested to elect product claims instead of method claims made in previous response. Applicants' request was granted. As a result, claims 44-96 are pending and claims 82-96 are examined on the merits.

The requirement is deemed proper and is therefore made FINAL.

### ***Specification***

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The hyperlinks shown on the specification page 13, lines 6-7; page 18, lines 22-23 and lines 24-25; as well as page 24, line 17 need to be disabled.

### ***Claim Objections***

3. Claim 82 is objected to because claim 44 is not drawn to a duckweed plant culture or duckweed nodule culture. It is suggested to replace "of claim 44" with – produced according to --. Further, claim 82 is dependent on non-elected claim 44.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 82-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 44: the recitation, "enhancing the expression", renders the claims indefinite. It is unclear what reference it compares to. Does it compare to the expression from expression constructs without 5' leader sequence or with other 5' leader sequence such as native 5' leader sequence? Since the working examples provided do not show "enhanced expression", it is unclear what is the reference. The metes and bounds are unclear. Furthermore, the recitation, "5' leader sequence", renders the claims indefinite. It is unclear what part of the sequence of a ribulose-bis-phosphate carboxylase small

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subunit (RbcS) gene is considered to be 5' leader sequence. The metes and bounds are not clear. Claims 86 and 96, drawn to SEQ ID NO: 16 as the 5' leader sequence, however are immune to this rejection.

5. Claims 82-85, 87-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the full content of the specification indicates that obtaining 5' leader sequences from any RbcS genes are essential to the operation of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." (See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of

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the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

A review of the language of instant claims indicates that the claims are broadly drawn to a genus of any 5' leader sequences from any ribulose-bis-phosphate carboxylase small subunit (RbcS) genes. The only 5' leader sequence described in the specification is the SEQ ID NO: 16 from *Lemna gibba*. Not a single species differing in sequence from SEQ ID NO: 16 and having 5' leader sequence property is described in the specification. Although Buzby et al. (1990, *The Plant Cell* 2:805-814) teach upstream sequences of three RbcS genes from *L. gibba*, neither the prior nor the specification provide enough description on 5' leader sequences from any RbcS gene. The specification also fails to correlate the conserved structures of 5' leader sequence of RbcS genes with the function of those sequences. Therefore, given the lack of description of the representative species in the claimed genus, a person skilled in the art would conclude that applicants are not in possession of the claimed genus of the 5' leader sequences of RbcS genes.

6. Claims 82-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the 5' leader sequence of SEQ ID NO: 16 for expression of biological active polypeptide in duckweed, does not reasonably provide enablement for any 5' leader sequences from any RbcS genes, or the 5' leader sequence of SEQ ID NO: 16 for enhanced expression of any biological active polypeptide in duckweed (emphasis added). The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification teaches that human growth hormone (hGH), Fab fragment and mAb were expressed in duckweed (page 38-page 40) by using expression constructs in which the 5' leader from the ribulose-bis-phosphate carboxylase small subunit 5B (RbcS) gene of *Lemna gibba* is used as the 5' leader sequence (page 38, lines 5-8 and lines 28-30; page 17-18). The amounts of proteins produced before purification were estimated (page 38, lines 15-17; page 39, lines 8-10; and page 39, lines 19-21). The activities of expressed protein were confirmed by western blot analysis (page 38, lines 17-20; page 39, lines 12-14; page 39, lines 25-26).

However, the specification does not show enhanced expression by using the 5' leader sequence from the ribulose-bis-phosphate carboxylase small subunit 5B (RbcS) gene of *Lemna gibba* since there is no reference to compare with. Further more, even if the expressions of those proteins were enhanced in duckweed, it still does not enable any other proteins, given the teaching of Wong et al. that the ability of 5' untranslated leader sequences and translational fusions to increase gene expression is dependent on the coding sequences to which you are attached (page 91, 2<sup>nd</sup> paragraph of right column, lines 7-11)

It is well known in the art that the effect of a 5'-UTL may vary depending on the plant, particularly between dicots and monocots (Dai et al. 2005, Transgenic Research 14:627-643; page 640, 2<sup>nd</sup> paragraph of left column, lines 8-11). Therefore, undue experimentation would be required to practice the invention in duckweed using 5' leader

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sequence from RbcS gene of a monocot plant. Furthermore, even in the same plant of *Lemna gibba*, there are three RbcS genes disclosed by Buzby et al. with 5' leader sequences quite different in sequence (page 807, Figure 1). Only one of them was demonstrated as 5' leader sequence in the working examples. Silverthorne et al. (1990, *Plant Molecular Biology* 15:49-58) teach that there are at least RbcS genes in *Lemna gibba* (page 52, figure 1). Undue experimentation would also be required to determine whether other 5' leader sequences from RbcS genes of *L. gibba* can be used for the instant invention. Still further, Dai et al. teach that the effect of UTL depend also depends on the promoter it is operably linked. It is found that an overall average of E1 activity in the RA-chl transgenic plants, in which the UTL of AMV RNA4 replaced the UTL of the RbcS-3C, was three times higher E1 transcription and E1 protein accumulation than Rr-chl transgenic plant, whereas when the UTL of the mannopine synthase gene in Mac promoter was replaced with the UTL of AMV RNA4, the E1 protein activity and accumulation in the transgenic plant was 3-4 times lower than that in the Mm-chl transgenic plant (page 640, 2<sup>nd</sup> paragraph of the left column). See *Genentech Inc. v. Novo Nordisk, A/S* (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims, lack of further guidance and addition working example, the unpredictability of the art, undue experimentation would be required for a person skilled in the art to practice the invention in full scope.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 82-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stomp et al. (1999, WO 99/07210) further in view of Wong et al. (1992, Plant Molecular Biology 20:81-93), Buzby et al. (1990, The Plant Cell 2:805-814) and Stiekema et al. (1983, Nucleic Acid Research 11:8051-8061).

Stomp et al. teach a method of producing a biologically active recombinant polypeptide (page 9, lines 1-9) in a duckweed culture, where the nucleotide sequence comprising the coding sequence for the polypeptide is operably linked to a coding sequence for a signal peptide (page 12, lines 16-23) that directs secretion of the polypeptide into the culture medium (page 12, lines 16-23, and claim 49), and collecting the biologically active recombinant polypeptide from the culture medium (claim 49).

Stomp et al. also teach producing a biologically active recombinant polypeptide where

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the polypeptide is encoded by nucleotide sequence that has been modified for enhanced expression in duck weed (page 15, lines 18-28), a biologically active multimeric protein including mAb, hemoglobin, P450 oxidase and a mAb (page 9, lines 1-9, also claim 48 and 52), a mammalian polypeptide (page 9, lines 16-21), a therapeutic polypeptide (page 8, lines 2-5), a human growth hormone and alpha interferon (page 8, lines 16-19, also claim 12, 47 and 56). Stomp et al. also teach that the expression cassette may further contain 5' leader sequence to enhance translation (page 12, lines 3-15). Stomp et al. further teach that the transit peptide from duckweed *L. gibba* isolated by Stiekema et al. can be used as transit polypeptide for enhancing translation.

Stomp et al. do not teach 5' leader sequence from RbcS gene or 5' leader sequence SEQ ID NO: 16.

Buzby et al. (1990, *The Plant Cell* 2:805-814) teach upstream sequences of three RbcS genes from *L. gibba*, including the 5' leader sequence from RbcS 5B gene which encompasses SEQ ID NO: 16.

Wong et al. teach the 5' leader sequence from RbcS gene of *Arabidopsis*.

It would have been obvious to a person with ordinary skill in the art to modify the method of Stomp et al. by utilizing the 5' leader sequence of Buzby et al. from *L. gibba* or 5' leader sequence from RbcS gene of *Arabidopsis* of Wong et al. One would have been motivated to do so given the teaching of Stomp et al. that the expression cassette may further contain 5' leader sequence to enhance translation, the teaching of Wong et al. that the 5' leader sequence from RbcS gene of *Arabidopsis* can enhance expression

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of GUS activity (page 89, 2<sup>nd</sup> paragraph of right column). Furthermore, a 5' leader sequence of a RbcS gene from a duckweed *L. gibba* becomes an obvious choice given that the expression host is also a duckweed. The resulting modified method of Stomp et al. would obviously produce claimed stably transformed duckweed.

8. Claims 82-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stomp et al. (1999, WO 99/07210) further in view of Wong et al. (1992, *Plant Molecular Biology* 20:81-93), Buzby et al. (1990, *The Plant Cell* 2:805-814), Yu et al. (1995, U.S. Patent No. 5460952), Park et al. (1997, *The Journal of Biological Chemistry* 272:6876-6881) and Stiekema et al. (1983, *Nucleic Acid Research* 11:8051-8061).

Stomp et al. teach a method of producing a biologically active recombinant polypeptide (page 9, lines 1-9) in a duckweed culture, where the nucleotide sequence comprising the coding sequence for the polypeptide is operably linked to a coding sequence for a signal peptide (page 12, lines 16-23) that directs secretion of the polypeptide into the culture medium (page 12, lines 16-23, and claim 49), and collecting the biologically active recombinant polypeptide from the culture medium (claim 49).

Stomp et al. also teach producing a biologically active recombinant polypeptide where the polypeptide is encoded by nucleotide sequence that has been modified for enhanced expression in duck weed (page 15, lines 18-28), a biologically active multimeric protein including mAb, hemoglobin, P450 oxidase and a mAb (page 9, lines 1-9, also claim 48 and 52), a mammalian polypeptide (page 9, lines 16-21), a therapeutic polypeptide (page 8, lines 2-5), a human growth hormone and alpha

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interferon (page 8, lines 16-19, also claim 12, 47 and 56). Stomp et al. also teach that the expression cassette may further contain 5' leader sequence to enhance translation (page 12, lines 3-15). Stomp et al. further teach that the transit peptide from duckweed *L. gibba* isolated by Stiekema et al. can be used as transit polypeptide for enhancing translation.

Stomp et al. do not teach 5' leader sequence from RbcS gene, 5' leader sequence SEQ ID NO: 16 or signal peptide from rice  $\alpha$ -amylase set forth by SEQ ID NO: 6.

Buzby et al. (1990, *The Plant Cell* 2:805-814) teach upstream sequences of three RbcS genes from *L. gibba*, including the 5' leader sequence from RbcS 5B gene which encompasses SEQ ID NO: 16.

Wong et al. teach the 5' leader sequence from RbcS gene of *Arabidopsis*.

Yu et al. teach a rice  $\alpha$ -amylase comprising a signal peptide set forth by SEQ ID NO: 6 (SEQ ID NO: 3 nucleotides 2366-2458).

It would have been obvious to a person with ordinary skill in the art to modify the method of Stomp et al. by utilizing the 5' leader sequence of Buzby et al. from *L. gibba* or 5' leader sequence from RbcS gene of *Arabidopsis* of Wong et al., and also using the signal peptide of Yu et al. One would have been motivated to do so given the teaching of Stomp et al. that the expression cassette may further contain 5' leader sequence to enhance translation, the teaching of Wong et al. that the 5' leader sequence from RbcS gene of *Arabidopsis* can enhance expression of GUS activity (page 89, 2<sup>nd</sup> paragraph of right column), the teaching of Yu et al. that secretion into

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media of the plant cell cultures is a potential commercial source of medicines (column 1, lines 45-65) and the teaching of Park et al. that signal peptide from rice  $\alpha$ -amylase can be recognized and processed by various expression systems including yeast *Y. lipolytica* (at least abstract). Furthermore, a 5' leader sequence of a *RbcS* gene from a duckweed *L. gibba* becomes an obvious choice given that the expression host is also a duckweed. The resulting modified method of Stomp et al. would obviously produce claimed stably transformed duckweed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 82-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17 of U.S. Patent No.

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6,815,184 (hereafter '184) in view of Wong et al. (1992, Plant Molecular Biology 20:81-93), and Buzby et al. (1990, The Plant Cell 2:805-814).

Claims 16-17 of '184 are drawn to a method of producing biologically active  $\alpha$ -2b-interferon in a duckweed plant culture or a duckweed nodule culture and the stably transformed duckweed produced. SEQ ID NO: 3 in claim 16 of '184 encodes a rice  $\alpha$ -amylase signal polypeptide of SEQ ID NO: 6.

Claims 16-17 of '184 do not teach 5' leader sequence from RbcS gene.

Buzby et al. (1990, The Plant Cell 2:805-814) teach upstream sequences of three RbcS genes from *L. gibba*, including the 5' leader sequence from RbcS 5B gene which encompasses SEQ ID NO: 16.

Wong et al. teach the 5' leader sequence from RbcS gene of *Arabidopsis*.

It would have been obvious to a person with ordinary skill in the art to modify the method of instant claims of '184 by utilizing the 5' leader sequence of Buzby et al. from *L. gibba*. One would have been motivated to do so given the teaching of Wong et al. that the 5' leader sequence from RbcS gene of *Arabidopsis* can enhance expression of GUS activity (page 89, 2<sup>nd</sup> paragraph of right column). Therefore a 5' leader sequence of a RbcS gene from a duckweed *L. gibba* becomes an obvious choice given that the expression host is a duckweed. The resulting modified method would obviously produce claimed stably transformed duckweed.

10. Claims 82-96 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 8-10, 23, 26-

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29 of copending Application No. 10/794,615 (hereafter '615). Claim 3 of '615 is drawn to a method of producing a recombinant monoclonal antibody having effector's function in a duckweed plant culture or a duckweed nodule culture, comprising the steps of:

- (a) culturing within a duckweed culture medium a duckweed plant culture or a duckweed nodule culture, wherein said duckweed plant culture or said duckweed nodule culture is stably transformed to express said monoclonal antibody, and wherein said monoclonal antibody is expressed from one or more nucleotide sequences comprising a coding sequence for a chain of the monoclonal antibody, an operably linked coding sequence for a signal peptide that directs secretion of the monoclonal antibody, an operably linked 5' leader sequence, and an operably linked plant intron sequence that is inserted upstream of the coding sequence; and
- (b) collecting said antibody from the duckweed culture medium, the duckweed plant culture, or the duckweed nodule culture, wherein said coding sequence for the chain of the monoclonal antibody comprises between 70-100% *Lemna gibba*-preferred codons or *Lemna minor*-preferred codons.

Claims 27 and 28 of '615 further limit a signal peptide being SEQ ID NO: 6 of instant application and 5' leader sequence being the 5' leader sequence from RbcS 5B gene from *L. gibba* which encompasses SEQ ID NO: 16. Therefore the claims of '615 teaching all the limitations set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection.

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11. Claims 82-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/873846 (hereafter '846) in view of Wong et al. (1992, Plant Molecular Biology 20:81-93), and Buzby et al. (1990, The Plant Cell 2:805-814).

Claim 2 of '846 is drawn to The duckweed plant culture or duckweed nodule culture of claim 1, wherein said nucleic acid molecule has at least one attribute selected from the group consisting of:

- (a) duckweed-preferred codons in the coding sequence for said  $\alpha$ -2b-interferon peptide;
- (b) duckweed-preferred codons in the coding sequence for said signal
- (c) a translation initiation codon that is flanked by a plant-preferred translation initiation context nucleotide sequence, wherein said plant-preferred translation initiation context nucleotide sequence consists of the nucleotide sequence "ACC" or "ACA", wherein said context is positioned immediately adjacent to of the 5' end of the translation initiation codon;
- (d) an operably linked nucleotide sequence comprising a plant intron that is inserted upstream of the coding sequence; and
- (e) an operably linked 5' leader sequence.

Claim 21 further limit the signal polypeptide being rice  $\alpha$ -amylase signal peptide set forth of SEQ ID NO: 6 of instant application.

Claims of '846 does not specify the 5' leading sequence being the one from RbcS gene.

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Buzby et al. teach upstream sequences of three RbcS genes from *L. gibba*, including the 5' leader sequence from RbcS 5B gene which encompasses SEQ ID NO: 16.

Wong et al. teach the 5' leader sequence from RbcS gene of *Arabidopsis*.

It would have been obvious to a person with ordinary skill in the art to modify the method of instant claims of '184 by utilizing the 5' leader sequence of Buzby et al. from *L. gibba* or 5' leader sequence from RbcS gene of *Arabidopsis* of Wong et al. One would have been motivated to do so given the teaching of Wong et al. that the 5' leader sequence from RbcS gene of *Arabidopsis* can enhance expression of GUS activity (page 89, 2<sup>nd</sup> paragraph of right column). Furthermore, a 5' leader sequence of a RbcS gene from a duckweed *L. gibba* becomes an obvious choice given that the expression host is a duckweed. The resulting modified method would obviously produce claimed stably transformed duckweed.

This is a provisional obviousness-type double patenting rejection.

### ***Conclusion***

Claims 82-96 are rejected.


No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**ELIZABETH MCELWAIN**  
**PRIMARY EXAMINER**

